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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/374,554 | 08/13/99 | SHYJAN A | MRI-005CP2 |

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HM12/0410

| EXAMINER | |
|---|---|
| GOLDBERG, J | |
| ART UNIT | PAPER NUMBER |
| 1655 | 8 |

DATE MAILED: 04/10/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/374,554 | SHYLAN ET AL. | |
| | Examiner | Art Unit | |
| | Jeanine A Enewold Goldberg | 1655 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-40* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 4-5, 10-11, 13-14, 16-17, 19-20, 25-26, 28-29, 31, 34, 40, drawn to a method for determining whether an agent can be used to reduce the growth of cancer cells by obtaining a sample and determining whether cancer cells express sensitivity genes (Tables 8B, 10B and 11B) to identify an agent which can be used to reduce growth of cancer cells by detecting the amount of mRNA that is encoded by the sensitivity genes, classified in class 435, subclass 6.

II. Claims 1-2, 7-8, 10-11, 13-14, 16-17, 22-23, 25-26, 28-29, 31, 37, 40 drawn to drawn to a method for determining whether an agent can be used to reduce the growth of cancer cells by obtaining a sample and determining whether cancer cells express sensitivity genes (Tables 8B, 10B and 11B) to identify an agent which can be used to reduce growth of cancer cells by detecting the amount of protein present that is encoded by the sensitivity genes, classified in class 435, subclass 7.1.

III. Claims 3, 6, 12, 15, 18, 21, 27, 30, 32-33, 35-36, 40 drawn to a method for determining whether an agent cannot be used to reduce the growth of cancer cells by obtaining a sample and determining whether cancer cells express resistance genes (Tables 8A, 9A, 9B, 9C, 9D, 10A and 11A) to identify an agent which can be used to reduce growth of cancer cells by

detecting the amount of mRNA that is encoded by the resistance genes, classified in class 435, subclass 6.

IV. Claims 3, 9, 12, 15, 18, 24, 27, 30, 32-33, 38-40 drawn to a method for determining whether an agent cannot be used to reduce the growth of cancer cells by obtaining a sample and determining whether cancer cells express resistance genes (Tables 8A, 9A, 9B, 9C, 9D, 10A and 11A) to identify an agent which can be used to reduce growth of cancer cells by detecting the amount of protein present that is encoded by the resistance genes, classified in class 435, subclass 7.1.

2. For claims which appear in more than one group, the claim will be examined to the extent that it applies to the elected group.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I, II, III, and IV, are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps. The method of Group I is directed to a method for determining whether an agent can be used to reduce the growth of cancer cells by obtaining a sample and determining whether cancer cells express sensitivity genes (Tables 8B, 10B and 11B) to identify an agent which can be used to reduce growth of cancer cells by detecting the amount of mRNA that is encoded by the sensitivity genes. The method of Group II is drawn to a method for determining whether an agent can be used to reduce the growth of cancer cells by obtaining a sample and

determining whether cancer cells express sensitivity genes (Tables 8B, 10B and 11B) to identify an agent which can be used to reduce growth of cancer cells by detecting the amount of protein present that is encoded by the sensitivity genes. The method of Group III is drawn to a method for determining whether an agent cannot be used to reduce the growth of cancer cells by obtaining a sample and determining whether cancer cells express resistance genes (Tables 8A, 9A, 9B, 9C, 9D, 10A and 11A) to identify an agent which can be used to reduce growth of cancer cells by detecting the amount of mRNA that is encoded by the resistance genes. The method of Group IV is drawn to a method for determining whether an agent cannot be used to reduce the growth of cancer cells by obtaining a sample and determining whether cancer cells express resistance genes (Tables 8A, 9A, 9B, 9C, 9D, 10A and 11A) to identify an agent which can be used to reduce growth of cancer cells by detecting the amount of protein present that is encoded by the resistance genes. The methods of Groups I and III rely on the detection of the amount of mRNA while the methods of Group II and IV rely on the detection of the amount of protein present. The amount of mRNA present is not always predictable to the amount of protein which is present. Moreover, the methods of Groups I, II, rely on the detection of sensitivity genes while the methods of Groups III and IV rely on the detection of resistance genes. These two groups of genes have different properties such that some are sensitive and some are resistant. Thus, the detection of one group is not predictable to the other group. Therefore the methods are distinct over one another.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter, restriction for examination purposes as indicated is proper.

5. Upon the election of one of these patentably distinct methods, Groups I, II, III, and IV are further subjected to an election of species.

Claims 1-2, and 3 generic to a plurality of disclosed patentably distinct species comprising sensitivity and resistance genes.

Applicant is required under 35 U.S.C. 121 to elect **a single disclosed species,** namely a gene, for prosecution on the merits, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Enewold Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Thursday from 7:00AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Enewold Goldberg
April 9, 2001

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
4/9/01